MAY 29 2012

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: Ortho Solutions Limited
West Station Business Park
Spital Road
Maldon
ESSEX, CM9 6FF
United Kingdom

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
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DATE: January 30, 2012

TRADE NAME: **Ortho Solutions Trauma Plates for Osteosynthesis**

COMMON NAME: Bone Plates, Bone Screws & Washers System;
Compression Hip Screw System (CHS/SCS)

CLASSIFICATION: Smooth or threaded metallic bone fixation fastener (*per 21CFR888.3040*) – Screw, Fixation, Bone.

Single/multiple component metallic bone fixation appliances and accessories (*per 21CFR888.3030*) – Plate, Fixation, Bone; Washer, Bolt Nut; Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component.

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **HWC, HTN, KTT**

SUBSTANTIALLY EQUIVALENT DEVICES

'Bone Plates, Screws & Washers' aap Implantate AG (**K072411**)
'Fixation Plate and Screw System' Mahe Medical GmbH (**K102845**)
'CHS/SCS System' Smith & Nephew (**K993289, K921786, K895241**)
'CHS/SCS System' DePuy (**K946156**)
'CHS/SCS System' Howmedica (**K781762**)
'CHS/SCS System' aap Implantate AG (**K071852**)

Ortho Solutions Limited - 510(k) Summary – K120360:

DEVICE DESCRIPTION:

The *Ortho Solutions Trauma Plates for Osteosynthesis* consists of general predicate type trauma implant components commonly found with large companies with orthopedic markets in the United States. These 'general trauma implant devices' consist of the following categories:

1. **Bone Plates, Bone Screws and Washers System**
2. **Adult Compression Hip Screw (CHS/SCS) System**

A brief and concise description of each system is as follows:

1. Bone Plates, Bone Screws and Washers System: This implant system consists of a Mini Fragment System (MFS), a Small Fragment System (SFS), and a Large Fragment System (LFS).
The Mini Fragment System is composed of 2.7mm A.C.P Plates in various hole lengths. These mini plates are secured to bone using 1.5mm, 2.0mm, and 2.7mm Cortical Screws. All Mini Fragment System plates and screws are intended for use in small bone extremity skeletal anatomy. The Small Fragment System is composed of 1/3 Tubular, 3.5mm A.C.P., 3.5mm Reconstruction, 3.5mm Cloverleaf, and 3.5mm 'T' - Plates in various hole lengths, Left, Right, and Oblique configurations. These small fragment plates are secured to bone using 3.5mm and 4.0mm cortical and cancellous screws, self-tapping, partial, and fully threaded. A 7 x 3.6mm Washer is also offered. All Bone Screws with or without the washer can be used separate from the plates. All Small Fragment plates and screws are intended for use in small bone skeletal anatomy. The Large Fragment System is composed of 4.5mm Narrow A.C.P, 4.5mm Broad A.C.P., 'T', 'T-Buttress', and 'L-Buttress' Left & Right Angled Plates in various hole length configurations. These large plates are secured to bone using 4.5mm, 4.0mm Malleolar, and 6.5mm cortical and cancellous screws, self-tapping, partial, and fully threaded. A washer is also offered. All bone screws with or without the washer can be used separate from the plates. All large fragment plates and screws are intended for use in large and long bone skeletal anatomy. All bone plates, bone screws, and washers are made of surgical grade 316LVM Stainless Steel to ASTM F138. All plates, screws, and washers are offered '**sterile**' to the customer.

2. Adult Compression Hip Screw (CHS/SCS) System: This implant system consists of various angled (95^0 for SCS, 130^0, 135^0, and 150^0 for CHS) high strength forged plates in multiple hole lengths, various Lag Screw lengths with various length Compression Screws, and various length 4.5mm Cortical Screws for securing the plate to femoral bone. Associated guide pin, drills, and ancillary instrumentation is available. The system is intended for use in repair of fractures of the femoral hip neck/head and supra-condylar area of the skeletal femur. All components are manufactured of surgical grade 316LVM Stainless Steel to ASTM F138. All plates and screws are offered '**sterile**' to the customer.

INTENDED USE:

The ***intended use*** of the *Ortho Solutions Trauma Plates for Osteosynthesis* of fixation device(s) is to draw two or more aligned bone fragments together to facilitate healing.

Ortho Solutions *Bone Plates, Bone Screws and Washers System* is indicated for use in fixation of various fractured bones. Mini plates and screws 3.5mm or smaller are intended for use in small bones in the hand or foot and include the metacarpal, metatarsal, and phalange bones. Small and large plates and screws 4.0mm and larger are intended for use in large and long bones which can include the clavicle, scapula, pelvis, calcaneus, talus and long bones (humerus, ulna, radius, femur, tibia, and fibula) in the skeletal anatomy.

Ortho Solutions *Compression Hip Screw CHS/SCS System* is indicated for fracture fixation in the proximal and distal regions of the human anatomy skeletal femur. *Specific indications include*: intracapsular fractures of the femoral neck; trochaneric and subtrochanteric neck fractures; osteotomies for patients with diseases or deformities of the hip; hip arthrodesis; supracondylar fractures and distal femoral fractures.

The Ortho Solutions Trauma Plates for Osteosynthesis is not intended for spinal use.

EQUIVALENCE:

The Ortho Solutions Trauma Plates for Osteosynthesis is substantially equivalent to predicate systems from many orthopedic companies (as listed).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Ortho Solutions Trauma Plates for Osteosynthesis is Similar in Material, Geometry Design/Markings, and Indications to many predicate systems currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The Ortho Solutions Trauma Plates for Osteosynthesis is shown to be safe and effective for use as 'sterile' and for single-use in a surgical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ortho Solutions Limited
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

MAY 2 9 2012

Re: K120360
Trade/Device Name: Ortho Solutions Trauma Plates for Osteosynthesis
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS, HWC, HTN, KTT
Dated: April 26, 2012
Received: April 30, 2012

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORTHO SOLUTIONS

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Indications for Use

510(k) NUMBER: **K120360**

DEVICE NAME: **Ortho Solutions Trauma Plates for Osteosynthesis**

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120360

Prescription Use __X__ AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)